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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,297	10/27/2000	James M. Robl	P 0277165	3475

909 7590 05/16/2002

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/697,297	ROBL ET AL.	
	Examiner	Art Unit	
	Joseph Voitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

This application, filed October 27, 2000, claims benefit to provisional application 60/161,987, filed October 28, 1999.

Claims 1-38 are pending and currently under examination.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, 11, 12-16, 33-35, drawn to a method for producing pluripotent embryonic stem cells wherein a haploid cell in metaphase II from a haploid female cell is used, classified in class 800, subclass 21 (because an embryo is formed during the method steps) and class 435, subclass 455. It is noted claims 2 and 3 recite a 'blastomere' which is a diploid cell, however this is not a haploid cell as required in step (a) and step (b) or a cell at metaphase II, and thus is considered a non-working embodiment of the instantly claimed method.
- II. Claims 1-5, 10, 12-16, 33-35, drawn to a method for producing pluripotent embryonic stem cells wherein a haploid cell in metaphase II from a haploid male cell is used, classified in class 800, subclass 21 (because an embryo is formed during the method steps) and class 435, subclass 2. It is noted claims 2 and 3

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recite a 'blastomere' which is a diploid cell, however this is not a haploid cell as required in step (a) and step (b) or a cell at metaphase II, and thus is considered a non-working embodiment of the instantly claimed method.

- III. Claims 17-25, drawn to a method for producing pluripotent embryonic stem cells wherein a haploid cell in metaphase II from a diploid female cell is used, classified in class 800, subclass 21 (because an embryo is formed during the method steps) and class 435, subclass 455.
- IV. Claims 17-25, drawn to a method for producing pluripotent embryonic stem cells wherein a haploid cell in metaphase II from a diploid male cell is used, classified in class 800, subclass 21 (because an embryo is formed during the method steps) and class 435, subclass 2.
- V. Claims 26-28 and 32-35, drawn to pluripotent embryonic stem cells, classified in class 424, subclass 93.1.
- VI. Claims 29-31, drawn to differentiated embryonic stem cells, classified in class 424, subclass 93.1.
- VII. Claims 36-38, drawn to a method of identifying growth factors that induce differentiation into specific cell types, classified in class 435, subclass 4.

Claims 1-5, 12-16, 33-35, are generic to groups I and II, and will be examined to the extent to the extent they encompass the elected invention. Claims 17-25 are generic to groups III and IV, and will be examined to the extent to the extent they encompass the elected invention.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each group is directed to methods for generating pluripotent embryonic stem cells, however each of the methods of each of the groups are separate and distinct methods requiring different method steps to practice and may result in a different and distinct outcome. For example, groups I and II are drawn to use of haploid cells and differ from groups III and IV which use diploid cells. Thus, the groups differ in the materials need to practice the methods and result in a cell which contains different cellular material, *i.e.* 2N vs. 4N genetic material. Further, the specific method steps recited in each group of claims are different, and require different materials to practice. Groups I and III differ from II and IV regarding the specific sex of the animal needed to practice the method. In groups I and III the cell is from a female, and in groups II and IV the cell is from a male. Isolating and culturing cells at metaphase II from males and females would require different starting materials and require physically different method steps to obtain. Further, the activation of these cells would require different effector molecules and culturing steps. The differences between the inventions are further underscored by their divergent classification and independent search status.

Inventions I-IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

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different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the invention of group VII is drawn to a completely different method than that set forth in groups I-IV, requiring different materials and different method steps to practice. The differences between the inventions are further underscored by their divergent classification and independent search status.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of the inventions of groups V and VI are drawn to different types of cells, group V are pluripotent cells which are capable of becoming many different types of cells, and group VI are differentiated cells which have lost their capacity to differentiate. Each cell type is different and unique, and require different conditions for maintenance in culture, and would provide for different uses because of their phenotypic characteristics. The differences between the inventions are further underscored by their divergent classification and independent search status.

Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the pluripotent cells can be used to generate chimeric animals or to generated differentiated cells. Further, the method of group VII can use cells from various

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sources at various stages of commitment to differentiation and does not require highly pluripotent stem cells. The differences between the inventions are further underscored by their divergent classification and independent search status.

Inventions I-IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case pluripotential cells can be isolated by different methods, for example by their direct isolation from ICM of embryos generated by natural or *in vitro* fertilization. The differences between the inventions are further underscored by their divergent classification and independent search status.

Because these inventions are distinct for the reasons given above have acquired a separate status in the art as shown by their different classification and divergent subject matter restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Patsy Zimmerman whose telephone number is (703)305-3883.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach


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